

AMENDMENT UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE
GROUP 1655
PATENT APPLICATION

#12/R
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Nobuhiko OGURA

Appln. No.: 09/373,585

Confirmation No.:

Group Art Unit: 1655

Filed: August 13, 1999

Examiner: F. Lu

For: TEST PIECE, METHOD OF AND APPARATUS FOR MANUFACTURING THE TEST
PIECE AND METHOD OF AND SYSTEM FOR READING THE SAME

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ATTN: BOX AF
Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action dated April 25, 2001, please amend the above-identified application as follows: A Petition for a Three-Month Extension of Time and a Notice of Appeal are being filed concurrently herewith.

IN THE CLAIMS:

Claims 1, 3-5 and 8-13 are canceled without prejudice or disclaimer.

11/16/01
Please
enter
F. Lu

REMARKS

This amendment, submitted in response to the Office Action dated April 25, 2001, is believed to be fully responsive to each point of rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1 and 3-21 remain pending in the application, with claims 4-5 and 8-13 being withdrawn from further consideration at this time as being directed to a non-elected invention. Claims 1 and 3 have been rejected under 35 U.S.C. § 102 as being anticipated by Heyneker (U.S.P. 6,057,100). Claims 6-7 and 21 have been rejected under 35 U.S.C. § 103 as being unpatentable over Matson et al. (U.S.P. 5,429,807, hereafter "Matson") in view of Yamamoto (U.S.P. 5,145,548) and Heyneker. Claims 14-20 have been rejected under 35 U.S.C. § 102 or §103 in view of Stern (previously of record). Applicant cancels non-elected claims 4-5 and 8-13 from the application. Applicant also cancels claims 1 and 3 from the application. Applicant further respectfully submits the following arguments in traversal of the prior art rejections.

Applicant's invention relates to a test piece for biological analysis, an apparatus for formation of the test piece and a method of analysis. Detailed descriptions of the background and preferred embodiment of the invention are set forth in the February 5, 2001 Amendment at pages 6-8. Applicant refers the Examiner to this document for these descriptions. Similarly, Stern is described in the February 5 Amendment at page 8. Further to these descriptions, Applicant emphasizes that Stern describes a multiple axis scanning system.

Turning to the newly cited art, Heyneker describes forming an array of oligonucleotide arrays. Referring to Fig. 1A, a support surface 15 of formed with a set of strips containing

oligonucleotides. The oligonucleotides are spaced in perpendicular stripes 1-10, which may be formed with fibers, such as cut-up strips of the solid support material. Col. 5, lines 15-23.

Matson relates to an apparatus for forming biopolymer arrays on a solid support material. An applicator formed of a thick plate includes several parallel channels formed in a surface of the plate. The applicator is positioned against a solid support material with the surface having channels sealed against a surface of the support material. For each channel, reagents for synthesis are introduced into one end of the channel and collected from the other end. Under the pressure contact, biopolymers such as oligonucleotides are synthesized onto a surface of the support material from reagents introduced into the channels, forming a one-dimensional array of biopolymers with each biopolymer having an identical sequence. No movement is provided to either the thick plate or the support material in forming the one-dimensional array. The strands of nucleotides formed in the one-dimensional array are cleaved and collected in respective channels. As an alternative to cleaving, Matson further teaches that the support material may be placed in sealing contact with the plate to augment the biopolymer strands. In this case, the channels of the applicator are placed at an angle relative to the transferred biopolymers previously formed on the support material. A lift and rotation device, as illustrated in Fig. 6 of Matson, performs this repositioning function. Col. 6, lines 37-42.

Yamamoto relates to lamination and cutting materials for manufacturing ID cards and credit cards comprising laminate of stiff materials and a magnetic strip.

The Examiner maintains that the combination of Matson, Yamamoto and Heyneker teach or suggest each feature of independent claim 6. Applicant argues that the rejection is not supported for at least five reasons.

First, Yamamoto is drawn from non-analogous art. A reference may only be applied if a) it is in the same field of endeavor as the application or b) it is reasonably pertinent to the problem with which Applicant is concerned. With respect to element a) Yamamoto relates to the field of manufacturing identification cards whereas the present invention relates to forming a test array of biological substances. These are clearly different fields of endeavor. With respect to element b) Yamamoto relates to laminating sheets of rigid base materials with a magnetic strip and cutting the sheets into individual cards. By contrast, the present invention relates to applying microscopic binding agents on a flexible substrate, and cutting the substrate in a direction that is substantially perpendicular in which binding agents are formed on the substrate. At a minimum the tolerances used in the manufacture of identification cards is less stringent than that used for the present invention. Accordingly, Yamamoto does not meet either the first or second requirements for analogous prior art.

Second, assuming *arguendo* that Matson and Yamamoto may be properly combined, their combination does not teach or suggest each feature of claim 6. Claim 6 describes a conveyor that conveys either the applicator or the substrate relative to each other in a direction which is substantially perpendicular to the direction of the arrangement of applicators. The Examiner cites the positioning means of Matson as teaching the conveyor. However, the positioning means of Matson corresponds to a device that removes a support material off a channel-containing plate and rotates the plate relative to the support material. See Fig. 6 and

corresponding text at col. 6, lines 31-41. During this movement, the plate (applicator) and the support are not in contact with each other, and thus no transfer of agents occurs. By contrast, claim 6 describes a conveyor that provides relative movement between the applicator and the substrate while the applicator is applying binding agents.

Third, Applicant argues that Matson may be not modified to include the conveying means as described by claim 6. The Examiner contends that the plate including several parallel channels corresponds to the applicator of claim 6, and further implies that the rotation device of Matson Fig. 6 corresponds to the conveyor. In Matson, if the conveyor provided the relative movement while the applicators applied the lines of binding agents, then this would cause an intermittent pressure seal between the support material and the channels, causing smearing of the biopolymer materials on the support material. This obviously would result in a material that is unsuitable for any type of analysis because the reagents from different channels would combine together.

Fourth, the Examiner contends that it would be obvious to provide test strips such as that illustrated in Heyneker, using the cutting device of Yamamoto and modifying the Matson to include the cutting device. However, in Matson, analysis of a one-dimensional array of biopolymers comprises cleaving of the polynucleotide strands from the support material and collecting the strands in containers at the end of respective channels. Col. 6, lines 15-23. Thus, it would be unnecessary to provide any cutting of the one-dimensional array. In the event that a two-dimensional array is formed, it would not be beneficial to cut the array into strips as test pieces because each cell contains a different sequence. See Col. 6, lines 57-63 and Fig. 8. Moreover, the nature of the polynucleotides in Matson (formed on a derivatized polypropylene

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col. 4, lines 60-68) suggests a much more volatile formation than that described in Heyneker (covalent bonding to fibers). Therefore, one skilled in the art would not cut up the formations and substrate in Matson.

Fifth, the above arguments suggest that the Examiner is using impermissible hindsight reconstruction in maintaining the rejection. Therefore, Applicant argues that independent claim 6 is patentable for at least the above reasons. Claims 7 and 21 are patentable based on their dependency.

With regard to claims 14-20, the Examiner maintains that Stern teaches or suggests each feature of independent claims 14 and 17. The Examiner correctly concedes that Stern teaches conveying along multiple axes, and thus does not teach conveying in a single axis. The Examiner presently contends that “this limitation could be considered as inherent to the reference taught by Stern et al., since the scanning system could cause the light to linearly scan the strip-like test piece along multiples axes and the single axis could be considered as one species of multiple axes during the scanning process.” Office Action at pages 9-10. The Examiner’s rejection of claim 14 is not supported for at least three reasons.

First, the Examiner’s rejection is internally inconsistent to the extent that it relies on “inherent disclosure” yet categorizes the scanning in a single dimension as a possible occurrence, i.e., “could be inherent” or “could be considered as one species of multiple axes” scanning. It is well-settled that mere possibilities do not support inherency or prior art rejections. In re Robertson, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999).

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Second, the Examiner characterizes that a multiple axes scanning (or conveyance) is a more generalized concept than a single axis scanning (or conveyance). Therefore, in order to set forth a prima facie case of obviousness, the Examiner must cite a reference that includes the single-axis description. Until the Examiner sets forth a prima facie case, Applicant has no burden to show unexpected results. Therefore, the Examiner's suggestion that Applicant provide evidence of unexpected results is premature. Applicant would also point out that the single axis conveyance provides improved results by greatly simplifying the control, whereas Stern requires a more complex and time-consuming control. The construction and manufacturing of the claimed invention is also greatly simplified over the three-dimensional system of Stern.

Third, as a related matter, Applicant submits that the single axis scan described by claim 14 provides significant benefits over the three-dimensional scan of Stern. With the three-dimensional scan, the location of the plane may be caused to fluctuate due to changes in distance between a light receiving lens and the subject. By contrast, in a single axis control environment, the relative distance can be maintained in a more stable manner. As a benefit of the more stable structure, the scanning speeds of the single axis control can be made significantly higher than that of Stern. All of the above improvements result from the structure of a single axis of relative movement. Therefore, claim 14 is patentable for at least these reasons. Claims 15-16 are patentable based on their dependency. With further regard to claim 16, this claim describes scanning in a single direction. The above comments with regard to claim 14 and conveying in a single direction also apply to the scanning feature of claim 16.

With regard to claim 17, the Examiner contends that page 1 of the previously filed remarks indicated that claim 17 was unpatentable. No such statement is made at page 1, and

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typographical errors of the Examiner and prior response notwithstanding, claim 17 is clearly patentable over Stern for at least two reasons.

First, as discussed above, the Examiner's rejection is internally inconsistent to the extent that it relies on "inherent disclosure" yet categorizes the use of difference values as a possible occurrence, i.e. "could be used to detect interaction." It is well-settled that mere possibilities do not support inherency or prior art rejections. In re Robertson, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999). Until the Examiner sets forth a prima facie case, Applicant has no burden to show unexpected results. Therefore, the Examiner's suggestion that Applicant provide evidence of unexpected results is premature. Applicant would further point out that the use of a difference analysis between the binding agent and samples at different fluorescent values, for example, permits a determination of what organism is present in one sample and absent in another, thereby permitting diagnosis of the source of disease.

Second, the Examiner has failed to discuss where the difference analysis is suggested. The Examiner merely describes how Stern includes optical devices that detect different fluorescent wavelengths. There is no further teaching of how samples are compared. Therefore, independent claim 17 is patentable for at least these reasons. Claims 18-20 are patentable based on their dependency. Claims 19 and 20 further describe the single direction conveyance and scan, respectively, and thus are further patentable for the reasons set forth above for claims 14 and 16.

In view of the above, Applicant submits that claims 2, 6, 7 and 14-21 are in condition for allowance. Therefore it is respectfully requested that the subject application be passed to issue at

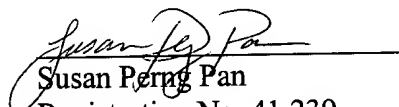
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the earliest possible time. The Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,

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